OCT 1 6 2002

Bio Med Sciences, Inc.

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Attachment 4

K023136

510 (k) Summary of Safety and Efficacy
Oleeva® Fabric

IDENTIFICATION

Device Name:
Oleeva Fabric
Common or Usual Name:
Elastomer, Silicone, for Scar Management

CLASSIFICATION

Class:
Previous silicone scar management products had been unclassified.
Classification Panel:
Previous silicone scar management products have been subject to the General & Plastic Surgery classification panel – Medical Specialty Code SU.
Product Code:
MDA

PRODUCT DESCRIPTION

Oleeva Fabric is used topically to reduce hypertrophic scars and keloids. Consistent use of Oleeva may minimize scars resulting from traumatic or surgical injuries. Oleeva can reduce existing scars, and may be used after traumatic or surgical injury to aid in the prevention of new scars.

INDICATIONS FOR USE

Oleeva Fabric is indicated for the management of hypertrophic scars and keloids. Consistent use of Oleeva Fabric can reduce hypertrophic scaring and keloid formation resulting from surgical or traumatic injury of the skin. Oleeva Fabric may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

SUBSTANTIAL EQUIVALENCE

The new device is substantially equivalent to the existing Oleeva Fabric product (K982036), Oleeva Foam (K002109), as well as the other silicone sheeting products manufactured by Bio Med Sciences, Inc.

BIOCOMPATIBILTY SUMMARY

Oleeva Fabric passes the following test protocols which were conducted in conformity to EN/ISO 10993 guidelines.

- Kligman Maximization
- Primary Dermal Irritation
- Agarose Diffusion Cytotoxicity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2002

Bio Med Sciences, Inc.
Mark E. Dillon
President
1111 Hamilton Street
Allentown, Pennsylvania 18101

Re: K023136
Trade/Device Name: Oleeva® Fabric
Regulation Name: Silicone sheeting for scar management
Regulatory Class: Unclassified
Product Code: MDA
Dated: September 19, 2002
Received: September 20, 2002

Dear Mr. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K02 3136

Attachment 2

Indications for Use Statement

510(k) Number (if known) Oleeva Fabric, 510(k) K982036,

Device Name Oleeva Fabric

Indications for Use

Oleeva Fabric is indicated for the management of hypertrophic scars and keloids. Consistent use of Oleeva Fabric can reduce hypertrophic scaring and keloid formation resulting from surgical or traumatic injury of the skin.

Oleeva Fabric may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

[As with the Predicate Device, we request OTC clearance for the modified device.]

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023136